Utah Department of Agriculture & Food 4315 South 2700 West TSOB South Bldg, Floor 2 Taylorsville, UT 84129-2128

## MEDICAL CANNABIS Independent Lab ESTABLISHMENT APPLICATION CHECKLIST

Website: <a href="www.ag.utah.gov">www.ag.utah.gov</a>
Phone: 801-982-2200
Email: cannabis@utah.gov

The Application submitted by a Cannabis Processing Facility and approved by the Establishment Board will be considered the business's operation plan. UDAF Inspectors will use the operation plan for regulatory purposes. Ensure all information is complete, current, and accurate.

The information provided by the applicant for a Medical Cannabis Production Establishment must fit within the following Guidelines:

- a) Maximum 50 pages
- b) Information provided must be clear and concise; do not repeat information
- c) Ensure each section speaks to the requested information; and are in the same order as application
- d) Everything in the application is contained in a single PDF document.

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# MEDICAL CANNABIS Independent Lab ESTABLISHMENT APPLICATION CHECKLIST

**Medical Cannabis Program** 

Application Number: \_\_\_\_\_\_\_\_(office use only)

An independent testing laboratory license allows the licensee to:

- a) Receive cannabis from a licensed cannabis cultivation facility to conduct testing as required by section 4-41a-701(2) and Utah Admin. Code R68-29.
- b) Receive cannabis from a licensed cannabis processing facility to conduct testing as required by section 4-41a-701(2) and Utah Admin. Code R68-29.
- c) Receive cannabis from a licensed cannabis cultivation facility and a cannabis processing facility to conduct the additional test as requested.

An Independent Testing Laboratory must pay a yearly licensing fee of \$15,000.00

	Ownership Information						
1.	Ownership Entity:						
	Entity Type:	Individual	Partnership	Corporation	Limited Liabilit	y Company	
2.	DBA: (assumed name o	f business)					
3.	Facility Address:						
		STREET		CITY	STATE	ZIP	
4.	Mailing Address:						
	(IF DIFFERENT)	STREET		CITY	STATE	ZIP	
5.	Business Phone:		Fax:	Other/off	ice:		
6.	Contact Person: _		Phone number:_	E	mail:		
7.	Manager:		Phone number:	Ema	nil:		
<u>8.</u>	8. Does the Independent Laboratory also do Industrial Hemp testing?						

9. Does this Independent Laboratory affiliated with any other Medical Cannabis Licenses?					
		Ownership Information			
production e who has the	establishment; or if the entity power to direct or cause the	is privately held, has a financial or voting intere is publicly traded has more than a 2% financial in management or control of a facility, in other wo	nterest in the company; or is	an individual	
List all Own	ers and their positions in the				
Lega	al Name (First & Last)	Role in the Company's Finances and Decisions	Listed on initial Application (Yes/ No)	Agent Card (Yes/ No)	
40 The second		Provident Control Control			
10. The applicant understands that as an applicant and potential licensee you are required to know the current statutory law, administrative rules and Departmental policies and comply in full? Yes No					
refere	•	ory shall employ a Scientific Director. <b>A copy</b> with application to provide proof that the sci			
A. Doctorate degree in chemical or biological sciences from an accredited college or university and have at least					
<ul><li>2 years of post-degree laboratory experience</li><li>B. Master's degree in chemical or biological sciences from an accredited college or university and have at least 4</li></ul>					
C.	years of post-degree laboratory experience.  C. Bachelor's degree in chemical or biological sciences from an accredited college or university and have a least				
6 years of post-degree laboratory experience					
12. Ownership / Management information, Utah Code 4-41a-204(b)					
A.	A. Descriptions of the credentials and experience of each Owner who has a financial or voting interest of 2% or greater and/or has direct decision making power over the cannabis production establishment				
В.	B. Provide a description of any investigation or adverse action taken by any licensing jurisdiction, government agency, law enforcement agency, or court in any state for any violation or detrimental conduct in relation to any of the applicant's cannabis-related operations or businesses.				
1					

### **Laboratory Facility Information**

13.	Laboratory	's Hours of	Operation:_	

### **Laboratory Establishment Property Information**

- 14. Submit a Blueprint with the following:
  - a) total square footage of the overall cannabis testing area;
  - b) location of toilet facilities;
  - c) location of handwashing facilities;
  - d) location of a break room;
  - e) location of personal lockers;
  - f) location of the areas to be used for receiving samples;
  - g) Show how areas of the facility are compartmentalized based on functionality; and
  - h) the location of all security cameras and external lights.

15.

- 16. Submit the proposed independent cannabis testing laboratory's written standard operating procedures for each test to be conducted. Provide the proposed independent cannabis testing laboratory's intended:
  - A. cannabis and cannabis product testing capability;
  - B. cannabis and cannabis product testing equipment;
  - C. testing methods, standards, practices, and procedures for testing cannabis and cannabis products.
- 17. Include a proposed Fee Schedule for all testing and services offered to Medical Cannabis Production Establishments.
- 18. Provide proof that the independent cannabis testing laboratory has thorough knowledge of and can follow validated analytical methods, equivalent to those published by AOAC, American Herbal Pharmacopoeia, EPA, FDA, or other reputable scientific organizations or request approval from the department for alternative scientifically valid testing methodology the lab is following for each required test.
- 19. Furnish evidence of the laboratory's International Organization for Standardization (ISO) 17025:2017 accreditation, or ability to become accredited with the International Organization for Standardization (ISO) 17025:2017 within 18 months.
- 20. Submit the laboratories adopted minimum good laboratory practices which satisfy the OECD Principles of Good Laboratory Practice and Compliance Monitoring, published by the Organization for Economic Co-operation and Development.

21.

- 22. Provide the proposed independent cannabis testing laboratory's employee training standards.
- 23. Detail the procedures the independent cannabis testing laboratory will employ to meet the transport and transfer requirements of Utah Code 4-41a-404 Cannabis. Including laboratory's sample transport and transfer plan in accordance with Utah Administrative Rule R68-30-8 Transportation.

- 24. Submit the proposed independent cannabis testing laboratory's security plan. Explain how the laboratory will operate in a facility that meets all security requirements in Utah Administrative Rule R68-30-5.
- 25. Describe the independent cannabis testing laboratory's inventory control system; include a description of how the inventory control system is compatible with the state electronic verification system. Detail the procedures the independent cannabis testing laboratory will employ to meet the Inventory Control System requirements of Utah Code 4-41a-103 Inventory Control System and Utah Administrative Rule R68-30-6 Inventory Control.
- 26. Provide the proposed independent cannabis testing laboratory's storage protocols, both short and long-term, to ensure all cannabis is stored in a manner that is sanitary and preserves the integrity of the cannabis.
- 27. Provide all written emergency procedures to be followed in case of fire, chemical spill and other emergencies at the laboratory.
- 28. Submit the proposed independent cannabis testing laboratory's waste disposal plan. Explain how the laboratory will operate in a facility that meets all requirements of Utah Code 4-41a-405 Excess and disposal and Utah Administrative Rule R68-30-9 Cannabis waste disposal.

#### **Operation Plan**

- 29. Submit, physical characteristics of the proposed facility, including a floor plan and an architectural elevation and written explanation:
- 30. Include a proposed Fee Schedule for all testing and services offered to Medical Cannabis Production Establishments.
- 31. Submit the proposed independent cannabis testing laboratory's written standard operating procedures for each test to be conducted. Provide the proposed independent cannabis testing laboratory's intended:
  - A. cannabis and cannabis product testing capability;
  - B. cannabis and cannabis product testing equipment;
  - C. testing methods, standards, practices, and procedures for testing cannabis and cannabis products.

32.

- A. How the independent cannabis testing laboratory shall compartmentalize all areas in the facility based on function;
- B. Shall limit access to the compartments to the appropriate authorized agents. location of toilet facilities and hand washing facilities;
- C. Location of a break room and location of personal lockers;
- D. location of the areas to be used for receiving samples;
- E. Total square footage of the overall cannabis testing area
- 33. Proximity: List any public or private school, a licensed child-care facility or preschool, a church, a public library, a public playground, or a public park located within 1000 feet by pedestrian travel to the proposed laboratory; or any district zoned as primarily residential within 600 feet by pedestrian travel to the proposed laboratory:

Compliance					
Compliance					
34. Provide proof of a \$50,000 performance bond that and intent to license has been issued.	a surety business in the state issues. This can be done after				
Applicant agrees as a condition of licensing that he/she has read and will abide by the provisions of Utah Code 4-41a and all rules promulgated thereunder and all directives of the Utah Department of Agriculture and Food. The applicant also understands that failure to adhere to maintain the qualifications of their license may result in in the suspension or revocation of the license and/or forfeiture of the performance bond.					
Applicant Agrees to immediately notify the department of any change in ownership or financial interest of the facility; the facility's name; change in location; change in testing methods, equipment, remodeling, expansion, reduction or physical, non-cosmetic alteration of the lab; or change in written operating procedures.					
The undersigned acknowledges that representatives of the Utah Department of Agriculture and Food may inspect the records and facility of a cannabis production establishment at any time during business hours to determine and ensure the cannabis production establishment is in compliance with the law. Failure to provide the department or the department's authorized agents immediate access to records and facilities during business hours in accordance with this section may result in a civil monetary penalty; license or registration suspension or revocation; or an immediate cessation of operations under a cease and desist order that the department issues.					
Disclaimer Applicant acknowledges and understands that cultivating, possessing, using, distributing and/or selling marijuana are prohibited by federal law, notwithstanding Utah law or any authorizations in the Agent or this Registration to the contrary. Nothing in this Application is intended to provide any guidance or assistance in violating or complying with existing federal laws regulating marijuana cultivation, distribution, or use. Similarly, compliance with state law or the terms of this Registration, or possession of the registration card does not confer immunity from enforcement of federal law or federal enforcement practices. Further, nothing in this Application or the Registration Card shall be construed as advice with regard to compliance with applicable federal, state, or local tax laws or any regulatory consequences of engaging in any business in this industry.					
The undersigned acknowledges that he/she has read and undone voluntarily and by the authorization of the applicant e	nderstands the statements herein and the execution thereof is entity.				
The undersigned hereby makes application to the Utah Department of Agriculture and Food and certifies that the information contained herein and attached here is true and correct.					
If selected for a license, applicant agrees to pay the \$15,000 license fee within 30 days of being notified of licensure decision.					
Applicant/Owner of business	Title/Position				
Applicant	Signature Date				